Legislation Summary Chart

Bill Number	Board Position 4/05	Leg Com. Recommended Position 7/13/05	Amendments	Current Status	Comments
AB 595	Support	Support	None	Senate Floor	
SB 1111	Support	Support	None	Assembly Floor	
AB 497	Support	Support	None	Senate Appropriations	
SB 734	Oppose Unless Amended	Oppose Unless Amended	Yes, but not accepted to date	Assembly Appropriations	
AB 21	None	Oppose	Yes	Senate Health, 2-year bill	6/15/05 version of the bill contains a provision regarding emotional distress and unprofessional conduct.
SB 644	Support	None		Assembly Appropriations	
AB 283	No Position	No Position	None	Senate B&P, 2-year bill	
SB 152	Oppose	Oppose	None	Senate B&P, 2-year bill	
AB 446	Support	Support	None	Senate Floor	
AB 657	Oppose	Support			
AB 522	Support if Amended	Support if Amended	Yes	Senate Floor	The proposed amendment would add the words "and dosage" to the bill.
SB 401	No Position	Oppose Unless Amended	Yes	Senate Health, 2-year bill	Recommend amending to: 1) allow a patient the ability to opt out of receiving paid advertisements with their medications; and 2) Require paid advertisement to be labeled as such and identify the sponsor of the advertisement.
SCR 19	None	Support	None	Assembly Rules Com.	
SB 798	None	Oppose Unless Amended	Yes		Proposed amendments would bring the measure in conformity with state

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

LEGISLATION AND REGULATION COMMITTEE

Legislation Report

FOR ACTION

Item 1 – AB 595 (Negrete McLeod) Pharmacy: Compounding of Prescription Drugs

Board Sponsored Bill
Committee Recommendation: Support
Version of Bill: 3/29/05
Current Version: 5/26/05

Summary: The bill would define compounding of a prescription drug for the purposes of the Pharmacy Law and would make other related changes in that regard.

A copy of the bill and committee analysis are in Attachment 1.

Item 2 – SB 1111 (B&P Committee) Omnibus Bill

Committee Recommendation: Support
Version of Bill: Introduced
Current Version: 5/11/05

Summary: This is a committee omnibus bill that includes eight changes the board is proposing for the Business and Professions Code. These change are:

1. Rules of Professional Conduct: B&P 4005 & 4206
2. Recast and Revision: Requirements For Designated Representatives: B&P 4053
3. Technical Updates to Licensing Provisions: B&P 4127.5, 4205 & 4400
4. Continuing Education Requirements: B&P 4231 & 4232
5. Pharmacist Recovery Program: B&P 4360-4373
6. Pharmacy Technician Program: B&P 4023.5, 4038, 4114, 4115, 4115.5 & 4202
7. Letter of Admonishment: B&P 4315
8. Impairment or Theft by Licensed Individuals: B&P 4104

These changes cover are being proposed to clean up previous legislation, update the law or respond to state and national trends in regulating pharmacies and pharmacists. All the proposals are non-controversial. They have been reviewed and discussed at least twice during a public meeting of the board, and have been approved by the board for sponsorship.

A copy of the bill, committee analysis, and pending amendments that will be incorporated in the measure over then next few weeks are in Attachment 2.

Item 3 – AB 497 (Negrete McLeod) Drug Wholesalers and Manufacturers: Nonresident Wholesaler License Surety Bond
Board Position: Support
Version of Bill: 4/19/0505
Current Version: 4/19/05

Summary: Existing law, operative January 1, 2006, to January 1, 2011, requires an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of $100,000, or an equivalent means of security, for each site to be licensed by the nonresident wholesaler through which dangerous drugs or dangerous devices are to be shipped, mailed, or delivered to a site located in California. This bill would instead require a single $100,000 surety bond, or an equivalent means of security, to be submitted by an applicant for the issuance or renewal of a nonresident wholesaler license.

A copy of the bill, the board's analysis, and committee analysis are in Attachment 3.

Item 4 – SB 734 (Torlakson) Controlled Substances
Committee Recommendation: Oppose Unless Amend
Version of Bill: 4/18/05
Current Version: 4/18/05

Summary: The bill is sponsored the Department of Justice. The author's intent is to make clean-up changes to facilitate the effective operation of the CURES, the prescribing and dispensing of controlled substances, and the program duties of the Bureau of Narcotics Enforcement.

Amendment: Add a provision that would effectively cap board's funding of CURES each year unless the board receives an appropriation augmentation sufficient to cover the additional cost billed by the DOJ.

A copy of the bill, the board's analysis, and committee analysis are in Attachment 4.

Item 5 – Right to Refuse to Fill a Prescription

AB 21 (Levine) Pharmacists: Practice Requirements
Note: This is a 2-year bill.
Committee Recommendation: Oppose
Version of Bill: 4/13/05
Current Version: 6/15/05

Summary: This bill would require a pharmacist to dispense a prescription except in specified circumstances. The bill would allow a pharmacist to decline on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request only if he or she satisfies certain conditions. The bill would make a violation of those provisions unprofessional conduct and would also make harassment, as specified, of a patient by a pharmacist unprofessional conduct , subject to disciplinary action by the board. (B&P 4069)

SB 644 (Ortiz) Dispensing Prescription Drugs And Devices
Committee Recommendation:
Version of Bill: 4/7/05
Current Version: 7/5/05

Summary: The bill would require a health care licentiate to dispense drugs and devices pursuant to a lawful prescription or order except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate. (B& P 733)

A copy of the bill, the board's analysis, and committee analysis are are Attachment 5.

Item 6 – Pseudoephedrine

AB 283 (Koretz) Pseudoephedrine: Retail Sale
Note: This is a 2-year bill.
Committee Recommendation: No Position
Version of Bill: 4/13/05
Current Version: 5/26/05

Summary: The bill would limit access to ephedrine and pseudoephedrine products by requiring a retailer to place the products in a locked cabinet, and that The retailer or employee of the retailer shall at all times act to prevent the theft or diversion of the products. AB 283 would place these provisions in H&SC 11100.01.

SB 152 (Speier) Pseudoephedrine
Note: This is a 2-year bill
Committee Recommendation: Oppose
Version of Bill: 4/18/05
Current Version: 4/18/05

Summary: The bill would require 1) pseudoephedrine products to be sold in a pharmacy and by a pharmacist or pharmacy technician; 2) pseudoephedrine to be stored in a locked area in view of the pharmacist; 3) limit the quantity of product sold to no more than nine grams of pseudoephedrine in a within any 30 day period; 3) the purchaser produce photo identification; and 4) the purchaser to sign a document with specific information about the transaction. SB 152 would place these provisions in B&P 4051.1.

A copy of the bill and the board's analysis are in Attachment 6.

Item 7 – AB 446 (NEGRETE MCLEOD) Settlement Agreements (Gag Clauses)
Note: The board supported similar legislation, AB 320, in 2003.
Committee Recommendation: Support
Version of Bill: 3/30/05
Current Version: 3/30/05

Summary: This bill is intended to close a loophole in current law that allows a licensee under the supervision of DCA to prohibit a consumer who settles a civil suit from also filing a complaint or otherwise cooperating with a regulator.

A copy of the bill and the board's analysis are in Attachment 7.

Item 8- SB 592 (Aanestad) Acute Care Hospitals: Inpatient Pharmacy Technician Services

Note: This is a 2-year bill.
Committee Recommendation: Support
Version of Bill: 3/29/05
Current Version: 3/29/05

Summary: Permits general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes.

A copy of the bill and the board's analysis are in Attachment 8.

Item 9 – AB 896 (Matthews) Clinical laboratories

Note: This is a 2-year bill.
Committee Recommendation: Support
Version of Bill: Introduced
Current Version: Introduced

Summary: This bill would authorize a pharmacist to serve as a laboratory director of a clinical laboratory that provides routine patient assessment procedures, as defined, under specified conditions.

A copy of the bill and the board's analysis are in Attachment 9.

Item 10 – AB 657 (Karnette) Pharmacies: Prescription Containers: Labels

Note: This is a 2-year bill.
Committee Recommendation: Support
Version of Bill: 4/13/05
Current Version: 6/21/05

Summary: Revises the prescription labeling requirement to require a container to be labeled with, among other things, the "intended purpose" for which the drug was prescribed, if the intended purpose is listed on the prescription.

A copy of the bill and the board's analysis are in Attachment 10.

Item 11 – AB 225 (Negrete McLeod) Electronic Prescription Information

Note: This is a 2-year bill.
Committee Recommendation: Support if Amended

Version of Bill: 4/7/05
Current Version: 4/7/05

Summary: This bill allows health care professionals to receive nonmonetary remuneration, in the form of hardware, software, or information technology and training services, necessary and used solely to receive and transmit electronic prescription information in accordance with the standards set forth in Section 1860D-4(e) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104), in specified circumstances.

Amendment: Require the prescriber, prior to the electronic transmitting of a prescription, to offer to transmit the prescription to a pharmacy of the patient's choice.

A copy of the bill, the board's analysis, and committee analysis are in Attachment 11.

Item 12 – AB 522 (Plescia) Automated drug delivery system
Committee Recommendation: Support if Amended
Version of Bill: 3/29/05
Current Version: 6/23/05

Summary: This bill provides clean-up language for AB 2184 (Chapter 342, Statutes of 2004), Automated Dispensing Devises. Additionally, the measure would prohibit the Department of Health Services (DHS) from paying for any prescription drug or other therapy to treat erectile dysfunction for registered sex offenders and authorize the Department of Justice to share information with DHS concerning registered sex offenders.

Amendment: Add the words "and dosage" to page 4, line 33 to read:

"After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to the drug and dosage as ordered by the prescriber and reviewed by the pharmacist and that is specific to the patient."

A copy of the bill, the board's analysis, and committee analysis are in Attachment 12.

Item 13 – SB 401 (Ortiz) Medical information: Pharmacies: Marketing
Note: This is a 2-year bill.
Committee Recommendation: Oppose Unless Amended
Version of Bill: 4/12/05
Current Version: 6/15/05

Summary: This bill would define marketing to include written communication that is provided by a pharmacy to a patient about a different drug or treatment than that being dispensed by the pharmacy and that is paid for, or sponsored by, a manufacturer, labeler, or distributor of prescription drugs.

Amendments: 1) Allow a patient the ability to opt out of receiving paid advertisements with their medications. 2) Required paid advertisement to be labeled as such and identify the sponsor of the advertisement.

A copy of the bill, the board's analysis, and committee analysis are in Attachment 13.

Item 14 – SCR 49 (Speier) Medication Errors Panel
This is a new bill introduced on June 15, 2005
Committee Recommendation: Support
Current Version: 6/30/05

Summary: This measure would create a panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. The measure would require the panel to convene by October 1, 2005, and to submit to the Senate Committee on Health a preliminary report by March 1, 2006, and a final report by June 1, 2006.

A copy of the bill and committee analysis are in Attachment 14.

Item 15 – SB 798 (Simitian) Prescription Drugs: Collection And Distribution Program
Committee Recommendation: Oppose Unless Amended
Current Version: 6/21/05

Summary: This bill would authorize a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies.

A copy of the bill, the board's analysis, and committee analysis are in Attachment 15.

Item 16 - SB 380 (Alquist) Drugs: Adverse Event Reporting
Committee Recommendation:
Current Version: 6/21/05

Summary: This bill would require a licensed health professional, (a physician and surgeon, dentist, or pharmacist), and a health facility, (a hospital or clinic), to report all suspected serious adverse drug events that are spontaneous or observed in medical practice to the FDA's MedWatch program.
A copy of the bill, the board's analysis, and committee analysis are in Attachment 16.

Item 17 –Other Bills for Consideration
Note: The board did not take a position on the following bills, but would like staff to watch for amendments.

A copy of the bill, the board's analysis, and committee or floor analysis (if available) are in Attachment 17.

AB 71 (Chan) Pharmaceuticals: Adverse Drug Reactions: Office of Ca. Drug Safety
Note: This is a 2-year bill.

Summary: This bill would establish the Office of California Drug Safety Watch, which would require the construction of a public database of adverse prescription drug reactions.

AB 72 (Frommer) Prescription Drugs: Clinical Trials
Note: This is a 2-year bill.

Summary: This bill would establish the Patient Safety and Drug Review Transparency Act in order to ensure that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers.

SB 19 (Ortiz) California Rx Program
Note: This is a 2-year bill.

Summary: This bill is sponsored by the Governor and would establish the California Rx Program to negotiate for lower price prescription drugs for lower income Californians.

AB 73 (Frommer) Prescription Drugs: Importation: Procurement
Note: This is a 2-year bill.

Summary: This bill would establish a state Web site to help patients purchase lower-cost prescription drugs from pharmacies in Canada, U.K., and Ireland.

AB 74 (Gordon) California Rx Prescription Drug Hotline

Summary: This bill would establish a hotline that state residents could call for information about state and federal prescription drug discount programs

AB 75 (Frommer) Pharmaceutical Assistance Program

Summary: This bill would establish a prescription drug discount program for low-income state residents

AB 76 (Frommer) Office of Pharmaceutical Purchasing

Summary: This bill would place the responsibilities of several state agencies under a new state Office of Pharmaceutical Purchasing to purchase prescription drugs.

AB 77 (Frommer) Medi-Cal: Clinics: Reimbursement

Summary: This bill revises the pharmaceutical goods and services reimbursement formula for federally qualified health centers and rural health clinics.

AB 78 (Pavley) Pharmacy Benefits Management

Summary: The bill would require a pharmacy benefits manager to make specified disclosures to its purchasers and prospective purchasers, including specified information about the pharmacy benefit manager's revenues.

Attachment 1

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AMENDED IN SENATE MAY 26, 2005

AMENDED IN ASSEMBLY APRIL 18, 2005

AMENDED IN ASSEMBLY MARCH 29, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 595

Introduced by Assembly Member Negrete McLeod

February 17, 2005

An act to amend Section 4051 of, to add Section 4019.5 to, to repeal Section 4033 of, and to repeal and add Section 4123 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 595, as amended, Negrete McLeod. Pharmacy: compounding of prescription drugs.

Existing law, the Pharmacy Law, provides for the licensing and regulation by the California State Board of Pharmacy of pharmacists, pharmacies, and other related practices and makes a violation of that law a crime. The Pharmacy Law defines various terms for its purposes, including "manufacturer."

This bill would delete the definition of manufacturer. The bill would define compounding of a prescription drug for the purposes of the Pharmacy Law and would make other related changes in that regard. Because the bill would specify requirements for compounded drug products under the Pharmacy Law, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.

Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4019.5 is added to the Business and Professions Code, to read:

4019.5. (a) "Compounding" means any of the following activities occurring in a pharmacy pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug.

(2) Altering the strength of a drug.

(3) Combining components or active ingredients.

(4) Preparing a drug product from bulk chemicals.

(b) "Compounding" shall not include the reconstitution of a drug pursuant to the manufacturer's direction for oral, rectal, or topical administration.

~~(c) This section shall not apply to over-the-counter drugs or nonprescription drugs.~~

SEC. 2. Section 4033 of the Business and Professions Code is repealed.

SEC. 3. Section 4051 of the Business and Professions Code is amended to read:

4051. (a) Except as otherwise provided in this chapter, it is unlawful for any person to compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

SEC. 4. Section 4123 of the Business and Professions Code is repealed.

SEC. 5. Section 4123 is added to the Business and Professions Code, to read:

4123. (a) A compounded drug product shall only be dispensed or furnished to a patient pursuant to a prescription meeting the requirements of Section 4040.

(b) A compounded drug product shall only be dispensed or furnished to a patient where the prescription has been generated solely within an established professional relationship between the prescriber, patient, and dispensing pharmacy.

(c) A pharmacy may conduct anticipatory compounding of a drug product in limited quantity, as defined by regulation of the board, before receipt of a prescription order for that drug product, where the quantity of each drug product compounded in anticipation of receipt of prescription orders is based on a documented history of receipt of prescription orders generated solely within an established professional relationship between prescribers, patients of the pharmacy, and the pharmacy.

(d) A pharmacy may contract with another pharmacy to compound drug products on behalf of its patients.

(e) A pharmacy may only base its anticipatory compounding on a documented history of prescription orders received for its own patients or customers, and not those patients or customers of pharmacies with which it has a contractual relationship.

(f) Notwithstanding any other provision of this chapter, a pharmacist may do both of the following:

(1) Compound a drug product pursuant to a prescription, for delivery to another pharmacy pursuant to a contract for the purpose of dispensing or furnishing the drug product to the patient named in the prescription, provided that the drug is not compounded prior to the receipt of the prescription.

(2) Repackage a drug previously dispensed to the patient at the request of the patient or the patient's agent.

~~(g) This section shall not apply to over-the-counter drugs or nonprescription drugs.~~

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because

the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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AB 595

As Amended: May 26, 2005

SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT

Senator Liz Figueroa, Chair
As Fiscal: Yes

SUBJECT: Pharmacy: compounding of prescription drugs.

SUMMARY: Defines compounding of prescription drugs and establishes standards for pharmacies that compound drug products for patients.

Existing law:

1)Provides for the licensing and regulation of pharmacists and pharmacies and the practice of pharmacy by the California State Board of Pharmacy (Board).

2)Defines "manufacturer" as a person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufacturers on the immediate premises where the drug or device is sold to the ultimate consumer.

3)Specifies that "manufacturer" shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription provided that the drug is not prepared prior to receipt of the prescription.

4)Specifies that "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.

5)Provides that it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription of a prescriber, as required, unless he or she is a pharmacist.

6)Requires that any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report the contractual arrangement to the Board within 30 days of commencing the

compounding.

7)Requires any pharmacy, in order to compound injectable sterile drug products, to obtain a license from the Board of Pharmacy to compound injectable sterile drug products and specifies other requirements as it pertains to compounding injectable drug products.

This bill:

1)Defines compounding as any of the following activities occurring in a pharmacy relating to a prescription:

a) Altering the dosage form, or delivery system of a drug;

b) Altering the strength of a drug;

c) Combining components of active ingredients; or,

d) Preparing a drug product from bulk chemicals.

2)Excludes from the definition of "compounding" the reconstruction of a drug pursuant to the manufacturer's direction of oral, rectal, or topical administration.

3)Requires that a compounded drug product be dispensed or furnished to a patient only pursuant to a prescription or where the prescription has been generated solely within an established professional relationship between the prescriber, patient, and dispensing pharmacy.

4)Allows a pharmacy to conduct anticipatory compounding of a drug product in limited quantity, as specified, and allows a pharmacy to base its anticipatory compounding on a documented history of prescription orders received for its own patients or customers, and not those patients or customers of pharmacies with which it has a contractual relationship.

5)Allows a pharmacy to contract with another pharmacy to compound drug products on behalf of its patients.

6)Allows a pharmacist to do both of the following:

a) Compound a drug product pursuant to a prescription, for delivery to another pharmacy pursuant to a contract for the purpose of dispensing or furnishing the drug product to the patient named in the prescription, as long as the drug is not compounded before receipt of the prescription; and,

b) Repackage a drug previously dispensed to the patient at

the request of the patient or the patient's agent.

7)Deletes the definition of manufacturer and the requirement for a pharmacy that contracts to compound a drug for parenteral therapy to report the arrangement to the Board.

8)Makes other technical non-substantive changes.

FISCAL EFFECT: According to the analysis of the Assembly Appropriations Committee, dated April 27, 2005, minor and absorbable costs to the Board.

COMMENTS:

1.Purpose. According to the Board, the sponsor of this bill, over the last ten years there has been an increase in compounding drugs by pharmacies. This increase in compounding activity and potential harm to the public from improperly compounded drugs makes it necessary for the Board to establish standards for pharmacies that compound drugs.

The Author states that compounding is a practice that is centuries old. In the 1950s, with the rise in large drug manufacturers, the practice began to decline. However, the need for specialized drugs to treat ailments that do not affect the public at large, and are therefore not profitable for large-scale manufacturers to produce, caused a resurgence in compounding drugs by pharmacies. It is estimated that compounding may make up one percent of the prescriptions filled. This increase in compounding was accompanied by news reports of people dying from improperly compounded drugs. Since 1990 the Food and Drug Administration (FDA) is aware of 200 adverse drug events involving 71 compounded drugs. In 2001 alone, three deaths and thirteen hospitalizations occurred following injection of a compounded drug that was contaminated with bacteria.

2.Background.

a) Drug Compounding. According to background information provided by the Author, drug compounding involves the mixing, combining, or altering of ingredients to create a customized medication for an individual patient. Some of the products commonly compounded include lotions, ointments, creams, gels, suppositories, and intravenously administered fluids and medications. Some compounded drugs, like intravenously administered chemotherapy drugs, are sterile products that require special safeguards to prevent injury or death to patients receiving them. These safeguards include cleaner facilities, specific training for pharmacy

personnel, and testing of the compounded drug for sterility. According to the FDA, compounding occurs because there are drugs for certain conditions that are not made by manufacturers and even if a drug is mass-produced for a medical condition, patients might need a custom-made version for various reasons. However, compounding has its risks. Background information revealed that several compounding cases resulted in serious illness and deaths and raised concerns about oversight to ensure safety and quality of compounded drugs.

b) Compounding Oversight and Development of this Proposal. According to the Board, the FDA and Department of Health Services (DHS) consider compounding by a pharmacy to be drug manufacturing. The DHS licenses and the FDA registers licensees' businesses engaged in certain compounding activities. Under federal and state law, any manipulation of a drug product or component, which alters its original state including repackaging or relabeling, constitutes manufacturing, including what has been traditionally considered pharmacy compounding. However, federal and state drug laws, including California's Pharmacy Law, recognize compounding as a proper function of pharmacy practice and exempt pharmacies engaged in legitimate compounding from licensure or registration as manufacturers. The Board has jurisdiction over anyone who handles or prepares a dangerous drug, whether for sale, retail or otherwise in California. The FDA and DHS have authority over manufacturing, including compounding, even by those exempt from licensure and registration, but, in the exercise of their discretion, both the FDA and DHS have chosen to target pharmacy compounding that occurs outside the bounds of traditional pharmacy practice and leave the day-to-day regulation of traditional pharmacy practices to state boards of pharmacy.

In 1992, FDA issued a compliance policy guide that delineated FDA's enforcement policy on pharmacy compounding. That guide remained in effect until 1997, when Congress enacted the Food and Drug Administration Modernization Act of 1997. The new law clarified the status of pharmacy compounding under federal law. The FDA Modernization Act of 1997 defined the limits of legitimate compounding and included a section exempting drugs compounded on a customized basis for an individual patient from key portions of the Food Drug and Cosmetic Act (FDCA), if certain criteria were met. However, a 2002 decision by the U. S. Supreme Court found the section dealing with drug compounding contained unconstitutional restrictions on commercial speech (i.e., prohibitions on soliciting prescription for and advertising specific compounded drugs) and held the entire section of

law as invalid. In May 2002, the FDA issued a compliance guide on pharmacy compounding to represent its current position which indicated that the FDA will generally defer to state authorities in dealing with less significant violations of the FDCA, and expects to work cooperatively with the states in coordinating investigations, referrals, and follow-up actions. The practical effect of the FDA's compliance policy was to delegate to states the authority to regulate drug compounding when it is done to meet the unique needs of individual patients.

As a result of the many activities related to compounding especially at the federal level, DHS requested clarification from the Board on how it determines when pharmacy compounding falls outside of the scope of pharmacy practice. In response the Board formed a "Workgroup on Compounding" comprised of pharmacists and FDA and DHS representatives to develop drug compounding proposals and the provisions of this measure were developed over a one-year period in a series of meetings. One of the outcomes that the workshop hoped to achieve was to develop a list of factors (similar to the FDA compliance guide) that would be considered by Board inspectors that may suggest that a pharmacy that claims to be compounding may actually be engaged in manufacturing. It was the Board's position that it wanted to provide uniformity in compounding in California to better regulate the practice to enhance public protection. Also, by solidifying the role of compounding in pharmacy practice, it may diminish the likelihood that pharmacies compounding within their practice of pharmacy will be required to register as manufacturers.

The workshop developed this legislative proposal and at the same time drafted regulations to be promulgated once the legislation is passed. The regulations will further establish the requirements for general compounding by pharmacies. They will require a master formula record for all compounded drug products, and specify that the pharmacist who compounds the drug assures that the drug product retains its strength, quality and integrity until dispensed, and that it is prepared, labeled, stored and delivered according to specified requirements. The regulations will also establish record keeping and labeling requirements, quality assurance specifications for the compounding process and the compounded drug product, and the requirements for facilities and equipments. The regulations will also mandate that the chemicals, drug products and components must be used and stored according to official United States Pharmacopoeia Compendia specifications, and require that the patient must be

informed that the drug product has been compounded and the pharmacy will be required to recall a drug product that is misbranded, adulterated, or has the potential for patient harm.

3. Previous Legislation. SB 293 (Torlakson), Chapter 827, Statutes of 2001, required the Board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy, required some pharmacies that compound these drug products to be specially licensed, and provided for inspection and investigations of compounding pharmacies. This 2001, legislation was the result of a case where contaminated drugs compounded in a pharmacy led to the deaths of three patients and the hospitalization of many others.

SUPPORT AND OPPOSITION:

Support: California State Board of Pharmacy (Sponsor)

Opposition: (None received as of June 15, 2005.)

Consultant: Bill Gage

Attachment 2

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AMENDED IN SENATE MAY 11, 2005

SENATE BILL No. 1111

Introduced by Committee on Business, Professions and Economic Development (Senators Figueroa (Chair), Aanestad, Campbell, Florez, Morrow, Murray, and Simitian)

March 30, 2005

An act to amend Sections 2053.6, 2230, 2234.1, 2741, ~~2760.1,~~ 3735, 3739, 4005, 4038, 4053, 4104, 4114, 4115, 4115.5, 4127.5, 4202, 4205, 4231, 4232, 4315, 4360, 4364, 4365, 4366, 4369, 4371, 4372, 4373, 4400, and 4850 of, to add Sections 3779 and 4023.5 to, to repeal Sections 3735.3, 3736, 3775.2, 3775.3, 4206, 4363, 4367, 4368, and 4370 of, and to repeal and add Sections 4361 and 4362 of, the Business and Professions Code, relating to professions and vocations, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 1111, as amended, Committee on Business, Professions and Economic Development. Professions and vocations.

Existing law provides for the regulation of various professions, including physicians and surgeons, nurses, respiratory care practitioners, and pharmacists.

This bill would revise and recast certain provisions regulating these professions. The bill would require the Division of Medical Quality to organize itself as 2 panels of 7 members. The bill would require an applicant for a license to practice respiratory care to successfully pass the national respiratory therapist examination. The bill would require a pharmacy to have written policies and procedures for detecting chemical, mental, or physical impairment among licensed individuals employed by or with the pharmacy. The bill would require a pharmacy to report certain information to the California State Board of

Pharmacy for the protection of the public. The bill would require the board to operate a pharmacists recovery program to rehabilitate pharmacists and intern pharmacists whose competence may be impaired due to abuse of alcohol, drug use, or mental illness. The bill would establish requirements for this program and require the board to contract with one or more qualified contractors to administer the program. Because the bill would increase fees under the Pharmacy Law that would be deposited into the Pharmacy Board Contingent Fund which is continuously appropriated, the bill would make an appropriation.

Because a violation of the bill with respect to pharmacists would be a crime, it would impose a state-mandated local program

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 2053.6 of the Business and Professions Code is amended to read:

2053.6. (a) A person who provides services pursuant to Section 2053.5 that are not unlawful under Section 2051 or 2052 shall, prior to providing those services, do the following:

(1) Disclose to the client in a written statement using plain language the following information:

(A) That he or she is not a licensed physician.

(B) That the treatment is alternative or complementary to healing arts services licensed by the state.

(C) That the services to be provided are not licensed by the state.

(D) The nature of the services to be provided.

(E) The theory of treatment upon which the services are based.

(F) His or her educational, training, experience, and other qualifications regarding the services to be provided.

(2) Obtain a written acknowledgement from the client stating that he or she has been provided with the information described in paragraph (1). The client shall be provided with a copy of the written acknowledgement, which shall be maintained by the person providing the service for three years.

(b) The information required by subdivision (a) shall be provided in a language that the client understands.

(c) Nothing in this section or in Section 2053.5 shall be construed to do the following:

(1) Affect the scope of practice of licensed physicians and surgeons.

(2) Limit the right of any person to seek relief for negligence or any other civil remedy against a person providing services subject to the requirements of this section.

SEC. 2. Section 2230 of the Business and Professions Code is amended to read:

2230. (a) All proceedings against a licensee for unprofessional conduct, or against an applicant for licensure for unprofessional conduct or cause, shall be conducted in accordance with the Administrative Procedure Act (Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code) except as provided in this chapter, and shall be prosecuted by the Senior Assistant Attorney General of the Health Quality Enforcement Section.

(b) For the purpose of exercising its disciplinary authority against a physician and surgeon pursuant to this chapter and the Administrative Procedure Act, the Division of Medical Quality shall organize itself as two panels of seven members. Two members of each panel shall be public members. For purposes of this article, "agency itself," as used in the Administrative Procedure Act, means a panel of the division as described in this subdivision. The decision or order of a panel imposing any disciplinary action pursuant to this chapter and the Administrative Procedure Act shall be final.

SEC. 3. Section 2234.1 of the Business and Professions Code is amended to read:

2234.1. (a) A physician and surgeon shall not be subject to discipline pursuant to subdivision (b), (c), or (d) of Section 2234 solely on the basis that the treatment or advice he or she rendered

to a patient is alternative or complementary medicine if that treatment or advice meets all of the following requirements:

(1) It is provided after informed consent and a good-faith prior examination of the patient, and medical indication exists for the treatment or advice, or it is provided for health or well-being.

(2) It is provided after the physician and surgeon has given the patient information concerning conventional treatment and describing the education, experience, and credentials of the physician and surgeon related to the alternative or complementary medicine he or she practices.

(3) It does not cause a delay in or discourage traditional diagnosis of a condition of the patient.

(4) It does not cause death or serious bodily injury to the patient.

(b) For purposes of this section, "alternative or complementary medicine" means those health care methods of diagnosis, treatment, or healing that are not generally used but that provide a reasonable potential for therapeutic gain in a patient's medical condition that is not outweighed by the risk of the health care method.

SEC. 4. Section 2741 of the Business and Professions Code is amended to read:

2741. An application for reexamination shall be accompanied by the fees prescribed by this chapter.

~~SEC. 5. Section 2760.1 of the Business and Professions Code is amended to read:~~

~~2760.1. (a) A registered nurse whose license has been revoked, or suspended or who has been placed on probation may petition the board for reinstatement or modification of penalty, including reduction or termination of probation, after a period not less than the following minimum periods has elapsed from the effective date of the decision ordering that disciplinary action, or if the order of the board or any portion of it is stayed by the board itself or by the superior court, from the date the disciplinary action is actually implemented in its entirety:~~

~~(1) Except as otherwise provided in this section, at least two years for reinstatement of a license that was revoked, except that the board may, in its sole discretion, specify in its order a lesser period of time provided that the period shall be not less than one year.~~

~~(2) At least two years for early termination of a probation period of three years or more.~~

~~(3) At least one year for modification of a condition, or reinstatement of a license revoked for mental or physical illness, or termination of probation of less than three years.~~

~~(b) The board shall give notice to the Attorney General of the filing of the petition. The petitioner and the Attorney General shall be given timely notice by letter of the time and place of the hearing on the petition, and an opportunity to present both oral and documentary evidence and argument to the board. The petitioner shall at all times have the burden of proof to establish by clear and convincing evidence that he or she is entitled to the relief sought in the petition.~~

~~(c) The hearing may be continued from time to time as the board deems appropriate.~~

~~(d) The board itself shall hear the petition and the administrative law judge shall prepare a written decision setting forth the reasons supporting the decision.~~

~~(e) The board may grant or deny the petition, or may impose any terms and conditions that it reasonably deems appropriate as a condition of reinstatement or reduction of penalty.~~

~~(f) The petitioner shall provide a current set of fingerprints accompanied by the necessary fingerprinting fee.~~

~~(g) No petition shall be considered while the petitioner is under sentence for any criminal offense, including any period during which the petitioner is on court-imposed probation or parole, or subject to an order of registration pursuant to Section 290 of the Penal Code. No petition shall be considered while there is an accusation or petition to revoke probation pending against the petitioner.~~

~~(h) Except in those cases where the petitioner has been disciplined for violation of Section 822, the board may in its discretion deny without hearing or argument any petition that is filed pursuant to this section within a period of two years from the effective date of a prior decision following a hearing under this section.~~

~~SEC. 6.~~

SEC. 5. Section 3735 of the Business and Professions Code is amended to read:

3735. Except as otherwise provided in this chapter, no applicant shall receive a license under this chapter without first successfully passing the national respiratory therapist examination conducted by those persons, and in the manner and under the rules and regulations, as the board may prescribe.

~~SEC. 7.~~

SEC. 6. Section 3735.3 of the Business and Professions Code is repealed.

~~SEC. 8.~~

SEC. 7. Section 3736 of the Business and Professions Code is repealed.

~~SEC. 9.~~

SEC. 8. Section 3739 of the Business and Professions Code is amended to read:

3739. (a) (1) Except as otherwise provided in this section, every person who has filed an application for licensure with the board may, between the dates specified by the board, perform as a respiratory care practitioner applicant under the direct supervision of a respiratory care practitioner licensed in this state provided he or she has met education requirements for licensure as may be certified by his or her respiratory care program, and if ever attempted, has passed the national respiratory therapist examination.

(2) During this period the applicant shall identify himself or herself only as a "respiratory care practitioner applicant."

(3) If for any reason the license is not issued, all privileges under this subdivision shall automatically cease on the date specified by the board.

(b) If an applicant fails the national respiratory therapist examination, all privileges under this section shall automatically cease on the date specified by the board.

(c) No applicant for a respiratory care practitioner license shall be authorized to perform as a respiratory care practitioner applicant if cause exists to deny the license.

(d) "Under the direct supervision" means assigned to a respiratory care practitioner who is on duty and immediately available in the assigned patient care area.

~~SEC. 10.~~

SEC. 9. Section 3775.2 of the Business and Professions Code is repealed.

~~SEC. 11.~~

SEC. 10. Section 3775.3 of the Business and Professions Code is repealed.

~~SEC. 12.~~

SEC. 11. Section 3779 is added to the Business and Professions Code, to read:

3779. For purposes of license verification, a person may rely upon a printout from the board's Internet Web site that includes the issuance and expiration dates of any license issued by the board.

~~SEC. 13.~~

SEC. 12. Section 4005 of the Business and Professions Code is amended to read:

4005. (a) The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations as follows: for the proper and more effective enforcement and administration of this chapter; pertaining to the practice of pharmacy; relating to the sanitation of persons and establishments licensed under this chapter; pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed; providing for standards of minimum equipment for establishments licensed under this chapter; pertaining to the sale of drugs by or through any mechanical device; and relating to pharmacy practice experience necessary for licensure as a pharmacist.

(b) Notwithstanding any provision of this chapter to the contrary, the board may adopt regulations permitting the dispensing of drugs or devices in emergency situations, and permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a state other than California where the person, if licensed in California in the same licensure classification would, under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.

(c) The adoption, amendment, or repeal by the board of these or any other board rules or regulations shall be in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

~~SEC. 14.~~

SEC. 13. Section 4023.5 is added to the Business and Professions Code, to read:

4023.5. For the purposes of this chapter "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.

~~SEC. 15.~~

SEC. 14. Section 4038 of the Business and Professions Code is amended to read:

4038. (a) "Pharmacy technician" means an individual who assists a pharmacist in a pharmacy in the performance of his or her pharmacy related duties, as specified in Section 4115.

(b) A "pharmacy technician trainee" is a person who is enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education.

~~SEC. 16.~~

SEC. 15. Section 4053 of the Business and Professions Code, as added by Section 7 of Chapter 857 of the Statutes of 2004, is amended to read:

4053. (a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.

(b) An individual may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development equivalent.

(2) He or she shall have a minimum of one year of paid work experience, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.

(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.

(e) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78–410).

~~SEC. 17.~~

SEC. 16. Section 4104 of the Business and Professions Code is amended to read:

4104. (a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for detecting chemical, mental, or physical impairment, as well

as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

(c) Every pharmacy shall report to the board, within 30 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.

(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.

(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual.

(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

(7) Any information supporting a reasonable suspicion that a licensed individual is chemically, mentally, or physically impaired to the extent it affects his or her ability to practice.

(8) Any information supporting a reasonable suspicion that a licensed individual has engaged in theft, diversion, or self-use of dangerous drugs.

(d) Anyone participating in good faith in the making of a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

~~SEC. 18.~~

SEC. 17. Section 4114 of the Business and Professions Code is amended to read:

4114. (a) An intern pharmacist may perform all functions of a pharmacist at the discretion of and under the direct supervision

and control of a pharmacist whose license is in good standing with the board.

(b) A pharmacist may not supervise more than two intern pharmacists at any one time.

~~SEC. 19.~~

SEC. 18. Section 4115 of the Business and Professions Code is amended to read:

4115. (a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist.

(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty.

(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(e) No person shall act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

(f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, and for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. No entity employing a pharmacist may discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(g) Notwithstanding subdivisions (a) and (b), the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. Nothing in this subdivision shall be construed to authorize a

pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (f).

(h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

~~SEC. 20.~~

SEC. 19. Section 4115.5 of the Business and Professions Code is amended to read:

4115.5. (a) Notwithstanding any other provision of law, a pharmacy technician trainee may be placed in a pharmacy to complete an externship for the purpose of obtaining practical training required to become licensed as a pharmacy technician.

(b) (1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the direct supervision and control of a pharmacist.

(2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.

(3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient or by engaging in other verification procedures that are specifically approved by board regulations.

(4) A pharmacist may only supervise one pharmacy technician trainee at any given time.

(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.

(c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no more than 120 hours.

(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to 320 hours. No more than 120 of the 320 hours may be completed in a community pharmacy setting or in a single department in a hospital pharmacy.

(d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in a course of instruction at the institution.

(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates his or her trainee status.

~~SEC. 21.~~

SEC. 20. Section 4127.5 of the Business and Professions Code is amended to read:

4127.5. The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products shall be five hundred dollars ($500) and may be increased to six hundred dollars ($600).

~~SEC. 22.~~

SEC. 21. Section 4202 of the Business and Professions Code is amended to read:

4202. (a) The board may issue a pharmacy technician license to an individual if he or she is a high school graduate or possesses a General Education Development equivalent, and meets any one of the following requirements:

(1) Has obtained an associate's degree in pharmacy technology.

(2) Has completed a course of training specified by the board.

(3) Has graduated from a school of pharmacy recognized by the board. Once licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician license must be returned to the board within 15 days.

(4) Is certified by the Pharmacy Technician Certification Board.

(b) The board shall adopt regulations pursuant to this section for the licensure of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of subdivision (a). Proof of the qualifications of any applicant for licensure as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.

(c) The board shall conduct a criminal background check of the applicant to determine if an applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(d) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.

~~SEC. 23.~~

SEC. 22. Section 4205 of the Business and Professions Code is amended to read:

4205. (a) A license issued pursuant to Section 4110, 4120, 4160, or 4161 shall be considered a license within the meaning of Section 4141.

(b) The board may, in its discretion, issue a license to any person authorizing the sale and dispensing of hypodermic syringes and needles for animal use.

(c) The application for a license shall be made in writing on a form to be furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of Article 9 (commencing with Section 4140) of this chapter.

(d) A separate license shall be required for each of the premises of any person who sells or dispenses hypodermic syringes or needles at more than one location.

(e) A license shall be renewed annually and shall not be transferable.

(f) The board may deny, revoke, or suspend any license issued pursuant to this article for any violation of this chapter.

~~SEC. 24.~~

SEC. 23. Section 4206 of the Business and Professions Code is repealed.

~~SEC. 25.~~

SEC. 24. Section 4231 of the Business and Professions Code is amended to read:

4231. (a) The board shall not renew a pharmacist license unless the applicant submits proof satisfactory to the board that he or she has successfully completed 30 hours of approved courses of continuing pharmacy education during the two years preceding the application for renewal.

(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal of a pharmacist license.

(c) If an applicant for renewal of a pharmacist license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed 30 hours of continuing pharmacy education, the board shall not renew the license and shall issue the applicant an inactive pharmacist license. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by complying with Section 704.

~~SEC. 26.~~

SEC. 25. Section 4232 of the Business and Professions Code is amended to read:

4232. (a) The courses shall be in the form of postgraduate studies, institutes, seminars, lectures, conferences, workshops, extension studies, correspondence courses, and other similar methods of conveying continuing professional pharmacy education.

(b) The subject matter shall be pertinent to the socioeconomic and legal aspects of health care, the properties and actions of drugs and dosage forms and the etiology, and characteristics and therapeutics of the disease state.

(c) The subject matter of the courses may include, but shall not be limited to, the following: pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, pharmacy jurisprudence, public health and communicable diseases, professional practice management, anatomy, histology, and any other subject matter as represented in curricula of accredited colleges of pharmacy.

~~SEC. 27.~~

SEC. 26. Section 4315 of the Business and Professions Code is amended to read:

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with this chapter or regulations adopted pursuant to this chapter, directing the licensee to come into compliance.

(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.

(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee may do either of the following:

(1) Submit a written request for an office conference to the executive officer of the board to contest the letter of admonishment.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.

(B) Prior to or at the office conference the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of admonishment.

(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of admonishment.

(2) Comply with the letter of admonishment and submit a written corrective action plan to the executive officer documenting compliance. If an office conference is not requested pursuant to this section, compliance with the letter of admonishment shall not constitute an admission of the violation noted in the letter of admonishment.

(d) The letter of admonishment shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) The licensee shall maintain and have readily available a copy of the letter of admonishment and corrective action plan, if any, for at least three years from the date of issuance of the letter of admonishment.

(f) Nothing in this section shall in any way limit the board's authority or ability to do either of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775, 1775.15, 1777, or 1778 of Title 16 of the California Code of Regulations.

(2) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

~~SEC. 28.~~

SEC. 27. Section 4360 of the Business and Professions Code is amended to read:

4360. The board shall operate a pharmacists recovery program to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug use, or mental illness. The intent of the pharmacists recovery program is to return these pharmacists and intern pharmacists to the practice of pharmacy in a manner that will not endanger the public health and safety.

~~SEC. 29.~~

SEC. 28. Section 4361 of the Business and Professions Code is repealed.

~~SEC. 30.~~

SEC. 29. Section 4361 is added to the Business and Professions Code, to read:

4361. (a) "Participant" means a pharmacist or intern pharmacist who has entered the pharmacists recovery program.

(b) "Pharmacists recovery program" means the rehabilitation program created by this article for pharmacists and intern pharmacists.

~~SEC. 31.~~

SEC. 30. Section 4362 of the Business and Professions Code is repealed.

~~SEC. 32.~~

SEC. 31. Section 4362 is added to the Business and Professions Code, to read:

4362. (a) A pharmacist or intern pharmacist may enter the pharmacists recovery program if:

(1) The pharmacist or intern pharmacist is referred by the board instead of, or in addition to, other means of disciplinary action.

(2) The pharmacist or intern pharmacist voluntarily elects to enter the pharmacists recovery program.

(b) A pharmacist or intern pharmacist who enters the pharmacists recovery program pursuant to paragraph (2) of subdivision (a) shall not be subject to discipline or other enforcement action by the board solely on the pharmacists or intern pharmacists entry into the pharmacists recovery program or on information obtained from the pharmacist or intern pharmacist while participating in the program unless the pharmacist or intern pharmacist would pose a threat to the health and safety of the public. However, if the board receives information regarding the conduct of the pharmacist or intern pharmacist, that information may serve as a basis for discipline or other enforcement by the board.

~~SEC. 33.~~

SEC. 32. Section 4363 of the Business and Professions Code is repealed.

~~SEC. 34.~~

SEC. 33. Section 4364 of the Business and Professions Code is amended to read:

4364. (a) The board shall establish criteria for the participation of pharmacists and intern pharmacists in the pharmacists recovery program.

(b) The board may deny a pharmacist or intern pharmacist who fails to meet the criteria for participation entry into the pharmacists recovery program.

(c) The establishment of criteria for participation in the pharmacists recovery program shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

~~SEC. 35.~~

SEC. 34. Section 4365 of the Business and Professions Code is amended to read:

4365. The board shall contract with one or more qualified contractors to administer the pharmacists recovery program.

~~SEC. 36.~~

SEC. 35. Section 4366 of the Business and Professions Code is amended to read:

4366. The functions of the contractor administering the pharmacists recovery program shall include, but not be limited to, the following:

(a) To evaluate those pharmacists and intern pharmacists who request participation in the program.

(b) To develop a treatment contract with each participant in the pharmacists recovery program.

(c) To monitor the compliance of each participant with their treatment contract.

(d) To prepare reports as required by the board.

(e) To inform each participant of the procedures followed in the program.

(f) To inform each participant of their rights and responsibilities in the program.

(g) To inform each participant of the possible consequences of noncompliance with the program.

~~SEC. 37.~~

SEC. 36. Section 4367 of the Business and Professions Code is repealed.

~~SEC. 38.~~

SEC. 37. Section 4368 of the Business and Professions Code is repealed.

~~SEC. 39.~~

SEC. 38. Section 4369 of the Business and Professions Code is amended to read:

4369. (a) Any failure to comply with the treatment contract, determination that the participant is failing to derive benefit from the program, or other requirements of the pharmacists recovery program may result in the termination of the pharmacist's or intern pharmacist's participation in the pharmacists recovery program. The name and license number of a pharmacist or intern pharmacist who is terminated from the pharmacists recovery program and the basis for the termination shall be reported to the board.

(b) Participation in the pharmacists recovery program shall not be a defense to any disciplinary action that may be taken by the board.

(c) No provision of this article shall preclude the board from commencing disciplinary action against a licensee who is terminated from the pharmacists recovery program.

~~SEC. 40.~~

SEC. 39. Section 4370 of the Business and Professions Code is repealed.

~~SEC. 41.~~

SEC. 40. Section 4371 of the Business and Professions Code is amended to read:

4371. The board shall review the pharmacists recovery program on a quarterly basis. As part of this evaluation, the board shall review files of all participants in the pharmacists recovery program.

~~SEC. 42.~~

SEC. 41. Section 4372 of the Business and Professions Code is amended to read:

4372. All board records and records of the pharmacists recovery program pertaining to the treatment of a pharmacist or intern pharmacist in the program shall be kept confidential and are not subject to discovery , subpoena, or disclosure pursuant to Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code. However, board records and

records of the pharmacists recovery program may be disclosed and testimony provided in connection with participation in the pharmacists recovery program, but only to the extent those records or testimony are relevant to the conduct for which the pharmacist or intern pharmacist was terminated from the pharmacists recovery program.

~~SEC. 43.~~

SEC. 42. Section 4373 of the Business and Professions Code is amended to read:

4373. No member of the board shall be liable for any civil damages because of acts or omissions that may occur while acting in good faith pursuant to this article.

~~SEC. 44.~~

SEC. 43. Section 4400 of the Business and Professions Code, as added by Section 50 of Chapter 857 of the Statutes of 2004, is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars ($340) and may be increased to four hundred dollars ($400).

(b) The fee for a nongovernmental pharmacy annual renewal shall be one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250).

(c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars ($155) and may be increased to one hundred eighty-five dollars ($185).

(d) The fee for regrading an examination shall be seventy-five dollars ($75) and may be increased to eighty-five dollars ($85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars ($115) and may be increased to one hundred fifty dollars ($150).

(f) The fee for a nongovernmental wholesaler license and annual renewal shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(g) The fee for a hypodermic license and renewal shall be ninety dollars ($90) and may be increased to one hundred twenty-five dollars ($125).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053 shall be one hundred eighty-five dollars ($185) and may be increased to two hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund seventy-five dollars ($75) of the fee.

(2) The fee for the annual renewal of a license as a designated representative shall be one hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund one hundred dollars ($100) of the fee.

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred fifty dollars ($150).

(j) The fee for a nonresident wholesaler's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(*l*) The fee for an intern pharmacist license shall be sixty-five dollars ($65) and may be increased to seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars ($20).

(m) The board may waive or refund the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars ($30).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars ($60) and may be increased to one hundred dollars ($100).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic permit is three hundred forty dollars ($340) and may be increased to four hundred dollars ($400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250) for each permit.

(r) The board shall charge a fee for the processing and issuance of a license to a pharmacy technician and a separate fee for the biennial renewal of the license. The license fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50). The biennial renewal fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars ($30).

~~SEC. 45.~~

SEC. 44. Section 4850 of the Business and Professions Code is amended to read:

4850. Every person holding a license under this chapter shall conspicuously display the license in his or her principal place of business.

~~SEC. 46.~~

SEC. 45. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a

crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Proposed Amendments to SB 1111

Page 9 of the bill:

SEC. 16. Section 4104 of the Business and Professions Code is amended to read:

4104. (a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for ~~detecting~~ addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

(c) Every pharmacy shall report to the board, within 30 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.

(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.

(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual.

(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

~~(7) Any information supporting a reasonable suspicion that a licensed individual is chemically, mentally, or physically impaired to the extent it affects his or her ability to practice.~~

~~(8) Any information supporting a reasonable suspicion that a licensed individual has engaged in theft, diversion, or self-use of dangerous drugs.~~

(d) Anyone ~~participating in good faith in the~~ making ~~of~~ a report authorized or required by this section shall have immunity

from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

SB 1111

As Amended: May 11, 2005

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS

Gloria Negrete McLeod, Chair

SB 1111 (Committee on Business and Professions)

SUBJECT : Professions and vocations.

SUMMARY : Makes several non-controversial, minor, non-substantive or technical changes to various miscellaneous provisions pertaining to regulatory boards of the Department of Consumer Affairs (DCA). Specifically, this bill :

1)Makes the following changes pertaining to the Medical Board of California (MBC):

a) Specifies that the MBC's Division of Medical Quality shall be comprised of two panels of seven members (to reflect the change in composition already made by previous legislation).

b) Makes updating and clarifying changes.

2)Makes the following changes pertaining to the Board of Registered Nursing (BRN): Deletes the 3-month limitation on how often an applicant may be reexamined.

3)Makes the following changes pertaining to the Board of Pharmacy (BOP):

a) Streamlines the pharmacist licensure procedure, removing the outdated rules of professional conduct.

b) Recasts and revises the requirements for designated representatives, the non-pharmacists who oversee the operations of drug wholesalers.

c) Makes several technical updates to pharmacy licensing provisions.

d) Establishes 30 hours of continuing education (CE) for license renewal; specifies that a pharmacist who fails to provide proof within 60 days of license renewal of CE completion will be issued an inactive license and barred from practicing pharmacy; and changes the requirement for the CE exemption from two years after graduation to the first renewal of a pharmacist license.

e) Changes the term "pharmaceutical education" to "pharmacy education."

f) Deletes the provision that would keep the identity of a licensee who voluntarily enters the pharmacist recovery program confidential from BOP and adds a provision that would prohibit BOP from taking enforcement action against a self-referred licensee based on his or her entry into the program or any information obtained from a licensee while participating in the program.

g) Deletes the provision that allows unlicensed personnel to act as pharmacy technicians for one year if they work in one the following departments: Department of Corrections, California Youth Authority, Department of Mental Health, Department of Developmental Services, or the Department of Veterans Affairs; makes technical amendments to the pharmacy technician program; and standardizes the level of supervision of a pharmacist over designated pharmacy staff to "direct supervision and control."

h) Deletes the requirement that a copy of a pharmacist's letter of admonishment be kept on the pharmacy's premises.

i) Requires pharmacies to notify BOP within 30 days of a pharmacist who engages in theft, diversion, or self use of dangerous drugs. Additionally, requires pharmacies to hand over evidence against pharmacists engaged in these activities.

4)Makes the following changes pertaining to the Respiratory Care Board (RCB):

a) Repeals unnecessary or outdated language and identifies the national examination required for licensure.

b) Repeals the authority for RCB to charge fees to CE providers.

c) Repeals the requirement for RCB to report fee increases.

d) Provides that printouts of license verifications via RCB's website may be relied upon.

5)Makes the following change pertaining to the Veterinary Medical Board (VMB): Clarifies that a licensee must display his or her license - not a copy - at the principal place of business.

EXISTING LAW:

1)Provides for the licensing and regulation of physicians by MBC.

2)Provides for the licensing and regulation of registered nurses by BRN.

3)Provides for the licensing and regulation of pharmacists by BOP.

4)Provides for the licensing and regulation of respiratory care therapists by RCB.

5)Provides for the licensing and regulation of veterinarians by VMB.

FISCAL EFFECT : Unknown

COMMENTS :

Purpose of this bill . This bill is one of three "committee bills" authored by the Senate Business and Professions Committee that are intended to consolidate a number of non-controversial provisions related to various regulatory programs governed by the Business and Professions Code, and generally located within DCA. Consolidating the provisions in one bill is designed to relieve the various licensing boards from the necessity and burden of having separate measures for a number of non-controversial revisions.

Many of the provisions make minor, technical and updating changes, while other provisions are substantive changes which are intended to improve the ability of the various licensing programs to efficiently and effectively administer their respective licensing laws.

Continuing Education . B&P Code Sections 4231 and 4232 establish BOP's authority to require continuing education as a condition for renewal of a pharmacist license. BOP has identified four technical and non-substantive amendments that would clarify CE requirements to licenses. The first amendment would establish CE requirements of at 30 hours, which is currently the amount required in regulations.

The second would modify the existing CE exemption from the first two years following graduation to the first renewal of a pharmacist license. This change would effectively exempt both recent graduates from California schools and pharmacists coming from outside of California who have recently taken the North American Pharmacy License Exam and the California Jurisprudence

Exam, from the CE requirement.

The third would establish that a pharmacist who fails to provide proof of completed CE within 60 days as part of a license renewal would be issued an inactive license and be prohibited from practicing until proof of the completed CE is presented to BOP. (A pharmacist cannot practice with an inactive license.) Clarification of the law is needed because some pharmacists pay their licensing renewal fees but do not provide proof of CE. Currently these licenses are in limbo; the renewal has not been completed because they have not submitted proof of CE, but BOP has the fee.

The fourth would be to change the term "pharmaceutical education" to "pharmacy education" in Section 4232, to reflect current terminology.

Pharmacist Recovery Program . B&P Code Sections 4360-4373 establish the Pharmacist Recovery Program. Most of the proposed changes to the program are minor, technical revisions to more closely conform the statute to the current operation of the program. However, some of the changes offer substantive changes to the existing program. The following summarizes the changes offered in each section:

Section 4360 adds a directive to operate the program and clarifies that BOP may allow intern pharmacists to participate in the program; Section 4361 eliminates unnecessary definitions; and Section 4362 recasts the provisions specifying who is eligible to enter the program and the terms of entry into the program. First, a licensee can be referred to the program instead of, or in addition to, disciplinary action. Second, a licensee can enter the program voluntarily. This largely reflects the current operation of the program.

The substantial change made is that licensees who enter the program voluntarily will not have their identities withheld from BOP. Current law indicates that such "self-referrals" are confidential and BOP is generally not informed of their identities. This "confidentiality" can be voided if the program administrator believes the licensee may present a threat to the public. However, participants sign a disclosure agreement upon entering the program that permits the program to release their identity to BOP. This statutory change would conform to existing practice by the program.

Letter of Admonishment . SB 361 (Figueroa), Chapter 539, Statutes of 2003, added Section 4315 to the Business and Professional Code. B&P Code Section 4351 authorizes the executive officer to issue a letter of admonishment for a violation of Pharmacy Law and requires that a licensee receiving

a letter keep a copy of the letter in the pharmacy that he or she works in for three years. This requirement is problematic for licensees who do not work regularly in the same pharmacy or in a pharmacy at all. BOP recommends deleting the requirement that a copy of a letter of admonishment be kept in a pharmacy.

Impairment or Theft by Licensed Individuals . B&P Code Section 4101 establishes policies and procedures regarding theft, diversion, and self use of dangerous drugs by a pharmacist. This provision will add new requirements that pharmacies: 1) have procedures to detect chemical, mental or physical impairments, as well as theft or self-use drugs by pharmacy employees; and 2) pharmacies report to BOP within 30 days specified acts involving theft, diversion, or self-use of drugs, mental or physical impairment of employees. The goal is to prevent individuals from merely resigning or being fired and going to work in another pharmacy when the problems continue many times unbeknownst to the new owner, thus placing the public at risk. BOP would like to strengthen its ability to collect information on pharmacists who have engaged in these activities. BOP proposes that pharmacies be required to notify BOP and handover evidence if a pharmacist is in violation of the law. The proposal includes a provision that would give immunity from any liability to a person, who in good faith makes a report to BOP.

REGISTERED SUPPORT / OPPOSITION :

Support

California State Board of Pharmacy

Opposition

None on file.

Analysis Prepared by : Ross Warren / B. & P. / (916) 319-3301

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Attachment 3

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AMENDED IN ASSEMBLY APRIL 19, 2005

AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 497

Introduced by Assembly Member Negrete McLeod

February 16, 2005

An act to amend Section ~~4161~~ *4162.5* of the Business and Professions Code, relating to pharmacy practices.

LEGISLATIVE COUNSEL'S DIGEST

AB 497, as amended, Negrete McLeod. Drug wholesalers and manufacturers: ~~licensure exemption.~~ *nonresident wholesaler license surety bond.*

Existing law, the Pharmacy Law, provides for the licensure and regulation by the California State Board of Pharmacy of pharmacies and other persons. Under that law, a person located outside of this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state at wholesale is considered an out-of-state distributor that must be licensed by the board prior to engaging in those activities. *Existing law, operative January 1, 2006, to January 1, 2011, requires an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of $100,000, or an equivalent means of security, for each site to be licensed by the nonresident wholesaler through which dangerous drugs or dangerous devices are to be shipped, mailed, or delivered to a site located in California.*

This bill would ~~exempt from this licensure requirement certain transactions between affiliated or related wholesalers, as defined~~ *instead require a single $100,000 surety bond, or an equivalent means*

of security, to be submitted by an applicant for the issuance or renewal of a nonresident wholesaler license.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

~~SECTION 1. Section 4161 of the Business and Professions Code, as added by Chapter 887 of the Statutes of 2004, is amended to read:~~

SECTION 1. Section 4162.5 of the Business and Professions Code is amended to read:

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000) ~~for each site to be licensed~~, or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars ($10,000,000) or less in which the surety bond shall be twenty-five thousand dollars ($25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars ($100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, 2011, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

~~4161. (a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.~~

~~(b) A nonresident wholesaler shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.~~

~~(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.~~

~~(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:~~

~~(1) Its agent for service of process in this state.~~

~~(2) Its principal corporate officers, as specified by the board, if any.~~

~~(3) Its general partners, as specified by the board, if any.~~

~~(4) Its owners if the applicant is not a corporation or partnership.~~

~~(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.~~

~~(f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.~~

~~(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.~~

~~(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident~~

~~wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.~~

~~(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.~~

~~(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.~~

~~(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a nonresident wholesaler.~~

~~(*l*) The registration fee shall be the fee specified in subdivision (f) of Section 4400.~~

~~(m) The licensure requirements of this section shall not apply to a nonresident wholesaler that ships, mails, or delivers dangerous drugs or dangerous devices solely to an affiliated or related wholesaler licensed by the board pursuant to Section 4160. For purposes of this subdivision, an affiliated or related wholesaler is one where the wholesaler shipping, mailing, or delivering the product and the wholesaler receiving the product are under common ownership and control of the same business entity.~~

~~(n) This section shall become operative January 1, 2006.~~

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 497 **VERSION: AMENDED APRIL 19, 2005**

AUTHOR: NEGRETE MCLEOD **SPONSOR: NEGRETE MCLEOD**

RECOMMENDED POSITION:

SUBJECT: DRUG WHOLESALERS AND MANUFACTURERS: LICENSURE EXEMPTION

Existing Law:

Requires an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of $100,000, or an equivalent means of security, for each site to be licensed by the nonresident wholesaler through which dangerous drugs or dangerous devices are to be shipped, mailed, or delivered to a site located in California. (This requirement will be operative January 1, 2006, to January 1, 2011.) (B&P 4162.5)

This Bill:

Revises the nonresident wholesaler license requirement to require an applicant to submit only one surety bond of $100,000, or an equivalent means of security, regardless of how many individual sites are licensed. (B&P 4162.5 Amended)

Comment:

1) Author's Intent. The author's intent is to provide clean up language for the wholesaler license requirement in last year's board sponsored AB 2628.

2) Amended April 19, 2005. The April 19, 2005 amendment was made at the request of the board. The previous versions of AB 497 would have exempted from the licensing requirements of B&P 4161, a nonresident wholesaler that ships, mails, or delivers dangerous drugs or dangerous devices into this state solely to an affiliated or related wholesaler licensed by the board pursuant to Section 4160.

3) Legislative History. In 2004 the board sponsored SB 1307 (Chapter 857, Statutes of 2004) Wholesalers and Manufacturers of Dangerous Drugs and Devices, and AB 2682 (Chapter 887, Statutes of 2004) Pharmacy: Out-of-State Wholesalers.

4) Support/ Opposition.

Support: Amerisource Bergen Corporation (Sponsor)
California State Board of Pharmacy
Cardinal Health
McKesson Corporation

Opposition: None on file.

5) History.

2005

June 20	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 6. Noes 0.).
June 13	In committee: Hearing postponed by committee.
May 26	Referred to Com. on B., P. & E.D.
May 16	In Senate. Read first time. To Com. on RLS. for assignment.
May 16	Read third time, passed, and to Senate. (Ayes 77. Noes 0. Page 1555.)
May 9	Read second time. To Consent Calendar.
May 5	From committee: Do pass. To Consent Calendar. (May 4).
Apr. 27	From committee: Do pass, and re-refer to Com. on APPR. With recommendation: To Consent Calendar. Re-referred. (Ayes 10. Noes 0.) (April 26).
Apr. 21	Re-referred to Com. on B. & P. by unanimous consent.
Apr. 20	Re-referred to Com. on HEALTH.
Apr. 19	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Apr. 12	In committee: Set, first hearing. Hearing canceled at the request of author.
Apr. 6	Re-referred to Com. on HEALTH.
Apr. 5	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 3	Referred to Coms. on HEALTH and B. & P.
Feb. 17	From printer. May be heard in committee March 19.
Feb. 16	Read first time. To print.

AB 497

As Amended: April 19, 2005

SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT

Senator Liz Figueroa, Chair
Fiscal: Yes

SUBJECT: Drug wholesalers and manufacturers: nonresident wholesaler license surety bond.

SUMMARY: Allows an applicant for a license as a nonresident wholesaler of pharmaceutical drugs to submit a single surety bond to cover each site to be licensed, rather than a surety bond to cover each individual site.

Existing law:

1)Provides for the licensing and regulation of pharmacies and pharmacists by the California State Board of Pharmacy (Board) in the Department of Consumer Affairs.

2)Requires a person located outside of this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state at wholesale to be considered as a nonresident wholesaler and to be licensed by the Board prior to engaging in those activities.

3)Requires, as of January 1, 2006 and until January 1, 2011, an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of $100,000, or other equivalent means of security, for each site to be licensed by the nonresident wholesaler through which dangerous drugs or dangerous devices are to be shipped, mailed, or delivered to a site located in California.

4)Specifies that a single surety bond or other equivalent means of security acceptable to the Board shall satisfy the above requirement for a bond for all licensed sites under common control, as defined.

5)Specifies that the purpose of the surety bond is to secure payment of any administrative fine imposed by the Board and any cost recovery that may be ordered pursuant to disciplinary action taken by the Board.

This bill provides that an applicant for a nonresident

wholesaler license would only have to submit a single $100,000 surety bond, or other equivalent means of security acceptable to the Board, instead of a bond or security for each site to be licensed.
FISCAL EFFECT: According to the Assembly Appropriations analysis dated May 4, 2005, there would be no state fiscal effect.

COMMENTS:

1. Purpose. This bill is sponsored by the AmerisourceBergen Corporation. According to the sponsor, this bill addresses a conflict in existing law that specifically requires a surety bond for each nonresident wholesaler's site, yet otherwise allows for a single surety bond for a multi-site nonresident wholesaler under the common control of a single entity, such as ownership by voting rights or contract. The sponsor indicates that this measure is a technical-clean up issue that remained from the passage of two bills from last year. The surety bond requirement imposed by those measures mistakenly applied the surety bond requirement to each licensed out-of-state wholesaler. The intent was to allow a national wholesale company with multiple licensed distribution centers to post a single bond to cover all of its licensed centers.

2. Previous Legislation. SB 1307 (Figueroa), Chapter 857, Statutes of 2004, changed the licensing requirements of pharmaceutical wholesalers by establishing bonding requirements, and required all prescription drugs to have a "pedigree," as defined, that tracks the ownership of drugs from the manufacturer to the ultimate ownership by the pharmacy. SB 1307 also gave the Board stronger enforcement tools for wholesaler violations of these new requirements. SB 2682 (Negrete McLeod), Chapter 887, Statutes of 2004, required out-of-state manufacturers and wholesalers of dangerous drugs and devices to comply with the same requirements as in-state wholesalers.

3. Arguments in Support. The California State Board of Pharmacy is in support of this measure and indicates that they consider this change as technical clean-up to SB 1307 and SB 2682. The surety bond requirement imposed by these measures mistakenly applied the surety bond requirement to each licensed out-of-state wholesaler, when the intent of those bills was to allow a national wholesale company with multiple licensed distribution centers to post a single bond to cover all of its licensed centers.

SUPPORT AND OPPOSITION:

Support:

AmerisourceBergen Corporation (Sponsor)
California State Board of Pharmacy
Cardinal Health
McKesson Corporation

Opposition: (None received as of June 15, 2005)

Consultant: Bill Gage

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Attachment 4

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